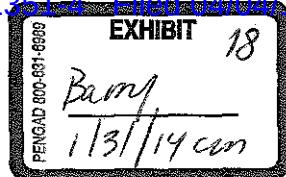


EXHIBIT 4

Message



Page 1 of 4

John Lehmann

From: John Lehmann [lehmann@lehmannthomas.com]
Sent: Thursday, April 15, 2004 3:07 PM
To: 'Lee Lynch'; 'Glass, Holly'; 'Passero, Donna'; 'Hudnall, Janet'; 'Jones, Kellee'
Cc: 'Kimberly Ocampo'
Subject: RE: Crisis Plan and Supporting Documents for your review

3:12-cv-00344-RCJ-WGC
Plaintiff's Exhibit

0682

exhibitsticker.com

Lee I have reviewed the various documents attached to your email.

My telephones are as follows:

O: 617 489 7080
 H: 508 358 5365
 C: 508 341 8942

Our overall simple message needs to be:

1. A properly placed filter can resist the force of a fair amount of blood clot, but that large clots and the forces of exertions such as bowel movements can overwhelm any filter's retentive capability, resulting in migration.
2. This is true for all IVC filters.
3. This leads into the two key facts in this case:
 - a. that the RF is a well designed and tested IVC filter that was properly placed and intact, and
 - b. that the blood clot was massive and additionally propelled by straining at stool.

==> Bottom line: good filter, severe case, bad outcome, deep regret.

This is the simple story we should repeat again and again.

Comparison with other filters is problematic in many ways, and we should avoid / downplay this as much as possible. When pressed, we simply paraphrase what was said in the Health Hazard, that "Estimates based on available data suggest that there is no significant difference in the rates of these complications between any of the devices currently marketed in the U.S., including the Recovery device."

As to review of the specific documents you forwarded:

The statement on page 20 Of the main communications plan as follows:

- o Extensive migration resistance testing conducted competitors showed that the Recovery Filter was just as resistant or more resistant to migration than all retrievable and non-retrievable competitors (MUST CONFIRM).

is not entirely accurate and does need revision. Should be discussed with BPV R&D and QA folks who've done the com at largest recommended IVC diameters the migration resistance drops substantially. BTW, I would think that the content herein does need review by John DeFord, Chris Ganser et al; I am presuming that you are doing this separately or at a later stage of drafting.

On page 21, the author has noted:

1. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event.

2/9/2006

Message

Page 2 of 4

[OR CAN WE SAY: While the Recovery Filter did migrate, we believe the underlying cause of death was the accumulation and migration of a very large pulmonary embolism. An enormous blood clot, measuring 10 cm in length and 3 cm in diameter, was deposited around the filter over a period of several days. The clot was of such a massive size that it enveloped the filter and traveled through the bloodstream to the man's lungs, causing death.]

From the point of view of patient privacy, it is confidential information regarding the pathological findings, cause of death etc., so I am not sure we are entitled to disclose such information, with the exception of prior legitimate disclosure by others (such as family members). I would guess (needs legal concurrence) that we can disclose the testing results that we have had performed in relation to the filter, such as the RF was entirely intact and functional. Whether we can mention blood clot or size of clot is a legal question relating to HIPAA issues etc.

For the Internal Q&A document, I would recommend changing #7 to the following text:

Pulmonary emboli are blood clots that form in large veins, such as those in the thigh, and then travel to the lungs. In the lungs, they block blood flow, which can cause shortness of breath, chest pain, faintness, low blood pressure, lung damage and in severe cases, sudden death. Such clots are particularly likely to form in a variety of unusual circumstances, including prolonged immobility, after hip surgery, after major traumatic injury and in obese individuals after weight reduction ("bariatric") surgery.

For the Internal Q&A document, the answer to Question #10 'who designed the RF' as 'NMT' is really not helpful to Bard, and certainly not to NMT. Bard bought, approved and sells the RF, and owns the design and its merits and demerits. Dinging NMT won't help the PR case, and will certainly piss off NMT. I'd find another way to handle this issue, such as "Bard purchased the product design and manufacturing from a valued partner, and has thoroughly assessed and tested the product, and stands behind its design in every way." or some such similar supportive and positive statement.

For the Internal Q&A document, Question #13 on physician training, be very careful on this one. It's not what you think you're doing, or what you told the FDA, but what you are actually currently doing. Get the straight story from the Sales force and don't dress it up.

For internal Q&A, Question #14 on complications, recommend changing to:

Potential complications observed for all types of inferior vena cava filters including the Recovery Filter include filter migration, perforation of the vena cava wall by filter legs, and vena caval occlusion or obstruction.

For Internal Q&A #15, the answer (text about various possible causes of migration) is not at all responsive to the question (about rate of migration for RF). The answer to #16 is the answer. Why don't you get rid of the A to #15 and the Q for #16, and combine the remains.

For Internal Q&A #17 - 18 on migration resistance testing, I wouldn't raise this subject if at all possible. It would be a most unusual reporter that will get this far. The testing data I saw in Arizona showed that altho RF was certainly within the boundaries of devices tested, in larger veins it was near the bottom. I would avoid as much as possible getting into this subject, because I'm not sure others would agree with the conclusion that "Recovery Vena Cava Filter was just as or more resistant to migration than all retrievable and non-retrievable competitors"

Internal QA& #19 ditto

Internal Q&A #20. I would change the text for #20 to:

Filter migration occurs whenever the force trying to move the filter exceeds the holding power of its fixation arms. A properly placed vena cava filter can constrain a significant amount of blood clot, but large blood clots can overwhelm the filter's retentive capabilities. Other recognized causes of filter migration include improper implantation technique, unusual patient exertion (such as straining at bowel movements) and

2/9/2006

Message

Page 3 of 4

fracture or failure of the filter wires. All marketed filters in the U.S. have reported instances of filter migration.

[If asked about Recovery Vena Cava Filter cases in which migration occurred, also add the following to the response: Of the six reported cases of the Recovery Filter migrating, five were caused by blood clots and one was caused by improper filter insertion.]

Internal Q&A #22 as follows:

1. *What are the dangers associated with filter migration?*

Most filter migrations are harmless to the patient and include filter movement of a few centimeters. In unusual cases, a filter containing a large amount of clot may migrate through the bloodstream to the lungs or heart. These complications can require surgical removal of the filter and clot, and rarely cause death. Without the filter, this amount of clot would have generally have passed directly to the lungs, causing substantial harm on its own.

Internal Q&A #24 - 27: I'd like to get a read on the HIPAA implications of discussing any clinical information regarding this patient. If we are able to discuss such things, then the text for these needs some significant revision. If not (which might be preferable) we have to say that we cannot discuss confidential patient information in response to all such questions as to causation, death certificates text, etc. Let's discuss once Donna has ruled on what disclosure is permissible in various circumstances.

External Q&A's:

#6 on what is a pulmonary embolus: see remarks above for Internal Q&A #7

#9 on training: see Internal Q&A #13 above

#10 on complications: see Internal Q&A #14 above

#12 on causes of filter migration: see Internal Q&A #20 above

#13 on comparative migration resistance: see multiple caveats above

An area that is not covered is the MAUDE database. If we get a reporter pressing questions on the number of reports, then we will have to deal with this sticky area. That means we have to have sales estimates, and tabulations of MAUDE entries (as already prepared by BPV staff) and calculations of rates; as well as someone comfortable with quantitative presentation skills and credibility.

RE medical literature summaries: can't comment, I'm on the road w/o the references. Practically speaking, we need to make sure that our physician spokespersons have all these references and the summary in a well organized binder, so that they can refer to them rapidly.

Hope this helps.

Regards, John Lehmann

From: Lee Lynch [mailto:LLynch@HillandKnowlton.com]
Sent: Tuesday, April 13, 2004 6:07 PM
To: 'Glass, Holly'; 'Passero, Donna'; 'John Lehmann'; Hudnall, Janet; 'Jones, Kellee'
Cc: Kimberly Ocampo
Subject: Crisis Plan and Supporting Documents for your review

2/9/2006

Message

Page 4 of 4

PRIVILEGED AND CONFIDENTIAL

Hi everyone -

Through conversations with Janet, Donna and Holly, we have secured enough information to create complete initial drafts of the Recovery Vena Cava Filter Crisis Plan and corresponding documents; each of these documents is attached for your review:

- Full Crisis Plan. Included in the Appendix section of the Crisis Plan are additional documents for your review, including:
 - General Key Messages
 - Miami incident-specific key messages
 - General Letter to the Editor
 - Miami incident-specific Letter to the Editor
- Internal Q&A
- External Q&A
- Medical Study Summaries

We'd like to ask you to review all of the documents this week, then join us for a call to go through your revisions sometime early next week. Can you let us know your availability on Monday and Tuesday of next week?

Questions for consideration and feedback are highlighted in yellow within the documents.

In addition, we have a number of questions we are hoping to have the following individuals answer directly to us by e-mail this week, including:

For Kellee Jones:

- Contact information for Chris Ganser and Doug Uelmen

For Janet Hudnall:

- Mobile number
- Is it OK to add Carol Stone under the key contact for the Field Sales Reps in the Audience Response Team section of the Crisis Plan?
- Are there any physicians NOT paid by Bard who can serve as spokespeople? If not, could you follow up with Drs. Venbrux and Kaufman regarding their interest and availability? To that end, please confirm that these physicians indeed have been paid by Bard for training and speaking.
- Is it OK to add the Society of Vascular Surgeons as an ally organization?
- Can you provide us with the following studies: Kaufman and Venbrux for FDA approval and the Special Access Canadian study?
- Are there any other human studies to add to the "Medical Study Summaries"?

Many thanks for your help! Lee Lynch and Kimberly Ocampo, H&K

2/9/2006